

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/800,328	BRIGHT ET AL.	
	Examiner Zachary C. Tucker	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 13 August 2007.

2.  The allowed claim(s) is/are 36-47,49 and 51.

3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All    b)  Some\*    c)  None    of the:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.

(a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.

(b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- 1.  Notice of References Cited (PTO-892)
- 2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
- 4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
- 5.  Notice of Informal Patent Application
- 6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
- 7.  Examiner's Amendment/Comment
- 8.  Examiner's Statement of Reasons for Allowance
- 9.  Other \_\_\_\_\_.

***Response to Amendment***

As requested in the correspondence from applicants filed 13 August 2007 (hereinafter “present amendment”), which is in reply to the Office action mailed 13 April 2007 (hereinafter “previous Office action”), claims 49 and 51 have been amended and claims 48 and 50 have been cancelled.

***Requirement for Restriction***

Because the present amendment has overcome the rejections of record, the nonelected claims are eligible for rejoinder. Claims that were indicated as having been withdrawn in the previous Office action specify methods whereby the products according to claims 36-47 are utilized. Since the methods specify an otherwise allowable product, then rejoinder is proper. Thus, the Requirement for Restriction, as was set out in the previous Office action, is hereby WITHDRAWN.

***Status of Claim Rejections - 35 USC § 112***

In the previous Office action, claims 36-47 were rejected under the first paragraph of 35 U.S.C. 112, for lack of enablement of the “solvates thereof” embodiment of the products. In view of applicants’ argument in traversal of the rejection, the rejection is hereby withdrawn.

Applicants’ argument stresses that in the context of the present invention, “solvate” is to be taken to mean “[a] compound of one or more molecules of a solvent with the ions or with the molecules of a dissolved substance,” which is only a very general nonspecific definition. A reference from Dorland’s Medical Dictionary was provided with the remarks to show the plain meaning of the word “solvate.”

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The rejection, however, was based on the contention that certain types of highly ordered crystalline solvates, wherein the solvent molecules are in specific ratios as compared to the compounds of the invention, are not actually taught in the instant specification, and certainly were not characterized and studied to any extent. Such solvates are described in the Gavezzotti and Vippagunta et al references which were provided with the previous Office action.

In the most general sense, though, as applicant's content, it is reasonable to propose that some amount of solvate of a compound must form on crystallization from a solvent. The specification does not teach how to identify and characterize the solvates formed, though, but identification and characterization is not absolutely necessary for some solvate formation and preparation to have been enabled by the specification.

***Allowable Subject Matter***

Claims 36-47, 49 and 51 are allowed.

The now-rejoined claims 49 and 51 are allowable, as the amendment to those claims limits the scope of which conditions and diseases are treated by the practice of the methods of those claims to the specific ones discussed in the Office action.

The closest prior art was described in the previous Office action.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

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Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



ZACHARY C. TUCKER  
PRIMARY EXAMINER